UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,719	11/17/2003	Janel E. Young	ETH5095	2358

25570 7590 02/24/2009

ROBERTS MLOTKOWSKI SAFRAN & COLE, P.C.
Intellectual Property Department
P.O. Box 10064
MCLEAN, VA 22102-8064

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
02/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

lgallaugher@rmsclaw.com
dbeltran@rmsclaw.com
bdiaz@rmsclaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/714,719	YOUNG ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt amendment and remarks filed 11/19/08. Claims 1 and 13 are amended. Withdrawn claims 14-41 are canceled. Claims 1 and 2 are amended. Claims 1-13 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn in view of the amendment to claims 1 and 2 and the cancellation of claims 1-13 of copending Application No. 10/797,367.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adachi et al. ("The prevention of Postoperative Intraperitoneal adhesions by Tranilast: N-(3',4'-dimethoxycinnamoyl) Anthranilic Acid) in Jpn. J. of Surg., (1999), 29, 51-54) in view of Hubbell et al. (US 6,461,640).

Adachi discloses administration of tranilast that inhibits adhesion, post operatively and preoperatively; administration is oral and the recitation of systemic in claims 12 and 13 reads on oral; tranilast is administered melted and in combination with carboxymethyl cellulose sodium (left column 52, first full paragraph) so that Adachi meets the delivery vehicle of claims 1-3; the recitation of "amounts … effective to inhibit formation of adhesion" represents any amount deemed effective by the artisan so that that requirement of claims 1 and 5; Adachi administers 60 mg/kg/per day, pre and post operatively, thus meeting claim 11; the recitation that the barrier is absorbable is a property of the barrier so that the teaching of Adachi that the tranilast is administered with the cellulose derivative, carboxymethyl cellulose sodium; meets the limitation of the barrier and thus meets claim 4; Adachi discloses that it is well known in the art that tranilast is effective drug for bronchial asthma, atopic dermatitis, allergic rhinitis, decreasing granulation, inhibit collagen synthesis of human cheloid tissue transplanted onto the backs of mice (page 52, under materials and methods); regarding claims 8-10, it is noted that Adachi teaches single dose per day administration and Adachi's silence on burst or sustained release of tranilast reflects an inherent teaching of either mode of release and the forms of release recited in claims 9 and 10 would flow from the composition that is administered and since Adachi administers the same composition as the claimed invention, it flows that the release of Adachi's formulation when administered meets the claimed release in claims 9 and 10. Regarding claim

7, one drug analog can be used in place of the other with the expectation of providing inhibitory effect on adhesions. Adachi teaches administration of composition containing tranilast to treat postoperative adhesions. Adachi does not administer the composition directly to surgical sites.

But Hubbell teaches that surgical adhesions such as post surgical adhesions are preventable or treated by topical administration of compositions comprising agents that inhibit adhesions (abstract; column 3, line 64 to column 4, line 14; claims 1-16). In Hubbell, the agents are hirudin, ancord and others (column 4, lines 23-33, claims 1-16). While the agents of Hubbell are not tranilast, the teachings of Hubbell and Adachi both show tranilast (Adachi), ancord and hirudin (Hubbell) as agents that inhibit adhesion. Therefore, taking the teachings of Adachi and Hubbell, one having ordinary skill in the art at the time the invention was made would have the option to topically or orally administer the agent for inhibiting or treating or preventing postoperative adhesion or surgical adhesion and expect that topical or oral administration of the agent would effectively inhibit of prevent surgical or postoperative adhesions.

4. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adachi et al. ("The prevention of Postoperative Intraperitoneal adhesions by Tranilast: N-(3',4'-dimethoxycinnamoyl) Anthranilic Acid) in Jpn. J. of Surg., (1999), 29, 51-54) in view of Hubbell et al. (US 6,461,640) and further in view of Sheffield et al. (EP 0 225 162).

5. Claims 1-5 and 7-13 are rejected above. However, the composition administered by the combined teaching Adachi and Hubbell does not contain anti-inflammatory agent as disclosed in claim 6. But Sheffield discloses topical administration of anti-inflammatory drug to inhibit post surgical adhesion (title, abstract, the whole document and specifically pages 1-7. Sheffield is

relied upon for teaching external administration of anti-inflammatory agents treat or inhibit adhesion.

6. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to topically or orally administer composition containing tranilast or other agents to inhibit adhesion according to Adachi in view of Hubbell. Thus, taking the general teachings of the prior Adachi in view of Hubbell and further in view of Sheffield, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that topically administration of compositions containing anti-inflammatory agents and tranilast and further systemic administration of tranilast in effective amounts would inhibit post surgical adhesion. One having ordinary skill in the art would have been motivated to use the combination of an anti-inflammatory agent and tranilast and expect the combination of the tranilast and the anti-inflammatory agent to inhibit adhesion upon oral or topical administration.

Response to Arguments

7. Applicant's arguments filed 11/19/2008 as they apply to the current rejections have been fully considered but they are not persuasive.

Applicant argues that Adachi failed to anticipate or render obvious the claims because Adachi does not administer delivery vehicle containing tranilast or its analog directly to the surgical site. The examiner agrees with the applicant that Adachi does not teach administration to the surgical site, but notes that that the rejection is not anticipation rejection, but rather combination of Adachi and Hubbell are used in the rejections under 35 USC 103; the teaching of the Hubbell cures that deficiency as described in the rejections above.

Applicant further argues Sheffield fails to teach Tranilast as an NSAID. While Sheffield does not name tranilast as an NSAID, it is noted that claim 6 selects the therapeutic agent of claim 5 from anti-platelet, ..., anti-inflammatory, …, such that any of the agents of the Markush group of claim 6 is needed to meet claim 6. Also, claim 6 does not state that tranilast is an NSAID and as such Sheffield should not be required to suggest or teach Tranilast as an NSAID in order for it to be art.

8. Therefore, applicant's arguments **have not been** found persuasive and the rejections are maintained.

No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618